UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.* MICHAEL I. LEVINE, M.D.,

Plaintiff,

٧.

VASCULAR ACCESS CENTERS, L.P., and each of its subsidiary and/or related corporations; JAMES McGUCKIN, M.D. (and any or all clinics owned, run, managed or operated by him); PHILADELPHIA VASCULAR INSTITUTE; ROBERT MATALON, M.D. (and any and all clinics owned, run, managed or operated by him); JOSEPH SHAMS, M.D.; NEW YORK DOWNTOWN HOSPITAL; BETH ISRAEL MEDICAL CENTER; AMERICAN ACCESS CARE, LLC; DAVITA, INC.; FRESENIUS MEDICAL CARE HOLDINGS, INC.; MICHAEL M. ABIRI, M.D.; TODD MARKOWITZ, M.D.; DANIEL MATALON, M.D.; ALBERT MATALON, M.D.; GREGG A. MILLER, M.D.; ALLEN WIESENFELD, M.D.; NEW YORK UNIVERSITY SCHOOL OF MEDICINE AND LANGONE MEDICAL CENTER; EDWARD Y. SKOLNIK, M.D.; ARTURO CONSTANTINER, M.D.; WARREN B. LICHT, M.D.; ANTHONY SMITH, M.D.; ALICE WEI, M.D.; GARY A. GELBFISH, M.D.; ALAN J. BOYKIN, M.D.; AXCESS GREAT NECK, LLC,

Defendants.

UNITED STATES OF AMERICA,

Plaintiff-Intervenor,

v.

VASCULAR ACCESS CENTERS, L.P., and each of its subsidiary and/or related corporations,

Defendants.

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DATE FILED: 10/19/2018

12 Civ. 5103 (LGS)

STIPULATION AND ORDER OF SETTLEMENT AND DISMISSAL WHEREAS, this Stipulation and Order of Settlement and Dismissal ("Stipulation") is entered into by and among plaintiff the United States of America (the "United States" or "Government"), by its attorney, Geoffrey S. Berman, United States Attorney for the Southern District of New York; the relator Michael I. Levine, M.D. ("Relator"), by his authorized representatives; and defendant Vascular Access Centers, L.P., and its subsidiary and/or related corporations (collectively, the "VAC Defendants," and together with the Government and Relator, the "Parties"), by its authorized representatives;

WHEREAS, on June 29, 2012, Relator filed a complaint (the "Relator Complaint") under the *qui tam* provisions of the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, alleging, among other things, that the VAC Defendants — along with James F. McGuckin, Jr., M.D. (and any or all clinics owned, run, managed or operated by him)² and Philadelphia Vascular Institute (together, the "Non-VAC Defendants") — had violated the FCA by improperly billing the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395–1395kkk-1

In addition to Vascular Access Centers, L.P., the VAC Defendants consist of Vascular Access Center of Atlanta LLC; Vascular Access Center of Atlantic County LLC; Vascular Access Center of Bolivar County LLC; Vascular Access Center of Central Jersey LLC; Vascular Access Center of Durham LLC; Vascular Access Center of Eatontown LLC; Vascular Access Center of Georgia LLC; Vascular Access Center of Houston LLC; Vascular Access Center of Jacksonville LLC; Vascular Access Center of Jersey City LLC; Vascular Access Center of Memphis LLC; Vascular Access Center of New Orleans LLC; Vascular Access Center of North Shore Louisiana LLC; Vascular Access Center of Pittsburgh LLC; Vascular Access Center of Prince George County LLC; Vascular Access Center of Seattle LLC; Vascular Access Center of South Atlanta LLC; Vascular Access Center of South Los Angeles LLC; Vascular Access Center of Southern Maryland LLC; Vascular Access Center of Southwest Louisiana LLC; Vascular Access Center of Trenton LLC; Vascular Access Center of Washington DC LLC; and Vascular Access Center of West Orange LLC (collectively, the "VAC Centers").

² These entities are James F. McGuckin M.D., Inc.; James F. McGuckin M.D. of MD, P.A.; James F. McGuckin M.D. of NC, P.A.; James F. McGuckin M.D. of NJ, P.A.; James F. McGuckin M.D. of TN, P.A.; James F. McGuckin M.D. of TX, P.A.; James F. McGuckin M.D. of TX, P.A.; James F. McGuckin M.D. of WA, P.C.; Main Line Vascular Institute, LLC; Penn Argyl Vascular Institute; Peripheral Vascular Institute of Philadelphia, LLC; Phoenixville Surgical Associates; Pocono Surgical Associates; and Vascular Access Centers, LLC.

("Medicare"), for noncovered vascular surgery procedures for patients with end-stage renal disease ("ESRD"), including angiograms or fistulagrams (diagnostic procedures for visualizing blood vessels) and percutaneous transluminal angioplasties (therapeutic procedures for repairing damaged blood vessels);

WHEREAS, the Government alleges that, from July 9, 2012, through December 31, 2016 (the "Covered Period"), the VAC Defendants violated the FCA by performing fistulagrams and percutaneous transluminal angioplasties on ESRD patients and billing Medicare for these procedures, even though the ESRD patients did not meet the criteria set forth in the applicable Local Coverage Determinations ("LCDs") for the procedures to be billed to Medicare (the "Covered Conduct");

WHEREAS, on July 9, 2018, the Government filed a Notice of Election to Intervene as against only the VAC Defendants, and on October 9, 2018, filed a corrected Notice to Intervene against only the VAC Defendants;

WHEREAS, contemporaneous with the filing of this Stipulation, the Government is filing a Complaint-In-Intervention in the above-referenced *qui tam* action (the "Government Complaint"), in which it is asserting claims against the VAC Defendants under the FCA and common law for the Covered Conduct;

WHEREAS, the Parties have, through this Stipulation, reached a mutually agreeable resolution addressing the claims asserted against the VAC Defendants in the Government Complaint and the Relator Complaint, for the Covered Conduct;

NOW, THEREFORE, upon the Parties' agreement IT IS HEREBY ORDERED that:

TERMS AND CONDITIONS

- 1. The Parties agree that this Court has subject matter jurisdiction over this action and consent to this Court's exercise of personal jurisdiction over each of them.
- 2. The VAC Defendants admit, acknowledge, and accept responsibility for the following conduct:
 - a. Vascular Access Centers, L.P., established in 2009, offers vascular medical and surgery services through the VAC Centers (see footnote 1, *supra*), which operated, during the relevant period, in twelve states and Washington, D.C.
 - b. Throughout the relevant period, most VAC Center patients were individuals with ESRD who regularly required and received dialysis. These patients required well-functioning vascular access in order to receive dialysis.
 - c. The VAC Centers provided ESRD-related vascular access services, including fistulagrams (a procedure to determine whether there are any blockages in blood vessels that could interfere with dialysis), and percutaneous transluminal angioplasties (a procedure to repair blockages in blood vessels).
 - d. VAC contracted with physicians to perform fistulagrams, angioplasties, and other procedures on ESRD patients at the VAC Centers.
 - e. In order to bill Medicare for a particular item or service, such as a fistulagram, VAC was required to follow the Medicare LCDs for that item or service applicable to the regions in which the VAC Centers operated. LCDs set forth the requirements for when a particular item or service is covered, and thus reimbursable, by Medicare.
 - f. For a provider to seek reimbursement for performing a fistulagram or related services on an ESRD patient, the LCDs for the regions in which the VAC Centers operated required that the patient have previously undergone a clinical examination that produced diagnostically specific and appropriate clinical findings demonstrating a need for therapies to reestablish physiologically appropriate flow in the dialysis fistula, and that such findings be documented in the patients' medical records.

- g. In the absence of such clinical findings suggesting the need to re-establish appropriate flow in a dialysis fistula, the LCDs provided that Medicare would not reimburse for fistulagrams or related procedures.
- h. The LCDs also provided that Medicare would not pay for services, including fistulagrams, that were only screening in nature.
- i. With respect to angioplasties, the LCDs generally provided that these procedures "will be considered reasonable and necessary when the documentation supports the presence of residual, hemodynamically significant stenosis, of greater than or equal to 50 percent of the vessel diameter," and further that "[a]ngioplasty of vessels not documented to be stenosed significantly (defined as greater than or equal to 50 percent) by angiography or ultrasound will be considered not medically necessary."
- j. The VAC Centers regularly scheduled ESRD patients for follow-up office visits before it was known whether the patients would exhibit clinical symptoms that would suggest the need to re-establish physiologically appropriate flow in their dialysis fistula.
- k. During these follow up visits and otherwise, the VAC Centers regularly performed, and billed Medicare for, fistulagrams on ESRD patients as a prophylactic or screening measure, even though the patients presented without any documented evidence that they exhibited a need for therapies to re-establish physiologically appropriate flow in the dialysis fistula, such as indications of difficulty with dialysis. During these follow up visits and otherwise, the VAC Centers also regularly performed, and billed Medicare for, angioplasties on ESRD patients where the patients displayed stenosis of greater than 50 percent of the vessel diameter, but presented without any other documented evidence that they exhibited a need for therapies to re-establish physiologically appropriate flow in the dialysis fistula, such as indications of difficulty with dialysis.
- 3. The VAC Defendants will pay each of the amounts set forth below to the United States on the corresponding dates set forth below (together, the "Settlement Payments"), of which any payments up to a total of nine million, one hundred eighty thousand, three hundred ninety-seven dollars (\$9,180,397) constitute restitution to the United States. The sum of the Settlement Payments that the VAC Defendants are to pay to the United States under the terms set forth below shall not exceed eighteen million, three hundred sixty thousand, seven hundred ninety-four dollars (\$18,360,794), plus interest accruing annually at a rate of 2.125% from July

- 9, 2018, to the date of the final Settlement Payment under the terms set forth below (the "Maximum Settlement Amount").
 - a. No later than fourteen business days from the Effective Date (defined in Paragraph 30 below) of this Stipulation, the VAC Defendants will pay the United States the sum of one hundred thousand dollars (\$100,000).
 - b. On January 1, 2019, and every three months thereafter to October 1, 2019 (*i.e.*, on April 1, 2019, July 1, 2019, and October 1, 2019), the VAC Defendants will pay the United States the sum of one hundred twenty-six thousand, two hundred fifty dollars (\$126,250) (four such payments totaling \$505,000).
 - c. On January 1, 2020, and every three months thereafter to October 1, 2023 (*i.e.*, on April 1, 2020, July 1, 2020, October 1, 2020, January 1, 2021, and so on), the VAC Defendants will pay the United States the sum of two hundred one thousand, two hundred fifty dollars (\$201,250) (sixteen such payments totaling \$3,220,000).
 - d. For each calendar year from 2019 to 2023, the VAC Defendants will (1) have a certified public accountant ("CPA") conduct a review or audit of their financial statements for the calendar year, and (2) pay to the United States 7.5 percent of any gross annual revenues they earn in the calendar year in excess of forty-eight million five hundred thousand dollars (\$48,500,000) within one month of when the CPA completes its review or audit, but in any event no later than May 15 of the following calendar year. For each calendar year from 2019 to 2023, the VAC Defendants will provide a copy of their reviewed or audited financial statements to the United States no later than May 15 of the following calendar year along with the necessary payment, if any, and a signed statement from the their CPA calculating the payment amount, if any, as well as explaining why and certifying that the payment amount is correct or that no payment is owed.
 - e. In the event that the VAC Defendants or their assets are transferred to or purchased by an outsider (meaning a person or entity that is not an equity holder, partner, officer or director of any VAC Defendant or controlled by such a person or entity) in a transaction that closes on or before December 31, 2023, the VAC Defendants will pay the following amounts to the United States in connection with each such transaction within fourteen business days from the closing date of the transaction. The VAC Defendants will provide copies of the executed transaction documents and a calculation certified by their CPA showing that the amounts paid are appropriate under the terms of this subparagraph, along with their payment to the United States.

- i. All unpaid amounts from subparagraphs (a), (b), and (c) above; and
- ii. A sum equal to the proportion listed below of the Net Sale Price:³
 - 1. For transactions closing on or before December 31, 2019, 50 percent of the Net Sale Price;
 - 2. For transactions closing between January 1 and December 31, 2020, 45 percent of the Net Sale Price:
 - 3. For transactions closing between January 1 and December 31, 2021, 40 percent of the Net Sale Price;
 - 4. For transactions closing between January 1 and December 31, 2022, 35 percent of the Net Sale Price; and
 - 5. For transactions closing between January 1 and December 31, 2023, 30 percent of the Net Sale Price.
- f. In the event that the VAC Defendants or all or substantially all of their assets are transferred to or purchased by an non-outsider (meaning a person or entity that is an equity holder, partner, officer or director of any VAC Defendant or controlled by such a person or entity) in a transaction that closes on or before December 31, 2023, the VAC Defendants will have a CPA prepare an appraisal of the fair-market value of the assets or shares sold or transferred (the "Appraised Sale Value"), which will be submitted to the United States along with the following payments that will

³ The "Net Sale Price" is the gross fair-market or, where an appraisal has been performed, appraised value of all consideration (including non-cash consideration in equity, debt, or otherwise) received by the VAC Defendants or their partners or equity holders in the transaction, less: (i) any amounts used to pay any bona fide debts to third parties that the VAC Defendants had incurred in the ordinary course of business in transactions that are not related to the sale or transfer transaction, (ii) any bona fide transaction costs associated with the sale or transfer transaction, and (iii) any "Preferred Return" paid to any person or entity making an "Investment" (defined as a new investment of cash in the VAC Defendants after the Effective Date of this Stipulation. The Preferred Return will be agreed upon by the VAC Defendants and the person or entity making the Investment, but in no event shall any Preferred Return for purposes of this definition exceed the amount of the Investment plus an annual rate of return of twenty-five percent (25%) compounded annually.

be paid in connection with each such transaction within fourteen business days from the closing date of the transaction:

- i. All unpaid amounts from subparagraphs (a), (b), and (c) above; and
- ii. A sum equal to the proportion listed below of the Net Appraised Sale Price:⁴
 - 1. For transactions closing on or before December 31, 2019, 50 percent of the Net Appraised Sale Price;
 - 2. For transactions closing between January 1 and December 31, 2020, 45 percent of the Net Appraised Sale Price;
 - 3. For transactions closing between January 1 and December 31, 2021, 40 percent of the Net Appraised Sale Price;
 - 4. For transactions closing between January 1 and December 31, 2022, 35 percent of the Net Appraised Sale Price; and
 - 5. For transactions closing between January 1 and December 31, 2023, 30 percent of the Net Appraised Sale Price.
- g. In the event that subparagraph (e) above is not triggered prior to December 31, 2023, but there is a transfer or purchase of more than 10% of any individual VAC Defendant or its assets, multiple VAC Defendants or their assets, or any other medical practice or practices owned or operated by any of the VAC Defendants, by an outsider (as defined in subparagraph (e) above) in a transaction that closes on or before December 31, 2023, the VAC Defendants will make the following payments to the United States in connection with each such transaction. The VAC Defendants will provide copies of the executed transaction documents and a calculation certified by

⁴ The "Net Appraised Sale Price" is the Appraised Sale Value, less: (i) any amounts used to pay any bona fide debts to third parties that the VAC Defendants had incurred in the ordinary course of business in transactions that are not related to the sale or transfer transaction, (ii) any bona fide transaction costs associated with the sale or transfer transaction, and (iii) any Preferred Return (defined in footnote 3) paid to any person or entity making an Investment (defined in footnote 3), provided that in no event shall any Preferred Return for purposes of this definition exceed the amount of the Investment plus an annual rate of return of twenty-five percent (25%) compounded annually.

their CPA showing that the amounts paid are appropriate under the terms of this subparagraph, along with their payment to the United States.

- i. The remaining VAC Defendants will continue to make the payments in subparagraphs (a), (b), (c), and (d) above according to the schedules set forth in those subparagraphs;
- The remaining VAC Defendants will pay, within fourteen ii. business days from the closing date of the transaction, a sum equal to the proportions listed in subparagraph (e)(ii) above of the Net Sale Price of the sold or transferred assets or entities,⁵ less any proceeds from the sale or transfer of assets or entities that are reinvested in the remaining VAC Defendants' business and actually used for business purposes within twenty-four (24) months of the asset sale. In the event the remaining VAC Defendants intend to reinvest all or part of the proceeds from such a sale or transfer, they may exclude the amount intended to be reinvested from their initial payment to the United States, but must, no later than thirty days after the conclusion of the twenty-four month deadline above, supplement their payment to the United States pursuant to this subparagraph if some or all of the amounts at issue were not timely reinvested.
- h. In the event that subparagraph (f) above is not triggered prior to December 31, 2023, but there is a transfer or purchase of more than 10% of any individual VAC Defendant or its assets, multiple VAC Defendants or their assets, or any other medical practice or practices owned or operated by any of the VAC Defendants, by a non-outsider (as defined in subparagraph (f) above) in a transaction that closes on or before December 31, 2023, the VAC Defendants will have a CPA prepare an appraisal calculating the Appraised Sale Value, which will be submitted to the United States along with the payment in subparagraph (iii) below for each such transaction, and will make the following payments according to the schedule set forth below:
 - i. The remaining VAC Defendants will continue to make the payments in subparagraphs (a), (b), (c), and (d) above according to the schedule set forth in those subparagraphs;

⁵ For purposes of computing the Net Sales Price under this subparagraph, deductions may be made only of the portion, if any, of bona fide debts to third parties directly related to the sold or transferred assets and of the Preferred Return on any Investment or portion of an Investment made in the sold or transferred assets.

- The remaining VAC Defendants will pay, within fourteen ii. business days from the closing date of the transaction, a sum equal to the proportions listed in subparagraph (f)(ii) above of the Net Appraised Sale Price of the sold or transferred assets or entities, 6 less any proceeds from the sale or transfer of assets or entities that are reinvested in the remaining VAC Defendants' business and actually used for business purposes within twenty-four (24) months of the asset sale. In the event the remaining VAC Defendants intend to reinvest all or part of the proceeds from such a sale or transfer, they may exclude the amount intended to be reinvested from their initial payment to the United States, but must, no later than thirty days after the conclusion of the twenty-four month deadline above, supplement their payment to the United States pursuant to this subparagraph if some or all of the amounts at issue were not timely reinvested.
- i. The VAC Defendants may terminate their continuing obligations to make payments under this Paragraph by making payments in the amounts below. The VAC Defendants may credit against the amounts below any amounts they have actually paid to the United States during the calendar year in which this payment is made. In the event that 40% or more of the VAC Defendants or their assets are sold or transferred (in a single or multiple transactions) within one year of a payment made under this subparagraph in a transaction that would otherwise trigger a payment obligation under subparagraphs (e)-(h) above, the VAC Defendants will make the payments required by subparagraphs (e)-(h), except that the payment under this subparagraph will be credited towards their payment obligations under subparagraphs (e)-(h).
 - i. On or before October 1, 2019, five million, nine hundred thousand dollars (\$5,900,000);
 - ii. Between October 2, 2019, and October 1, 2020, six million, seven hundred five thousand dollars (\$6,705,000);
 - iii. Between October 2, 2020, and October 1, 2021, seven million, five hundred ten thousand dollars (\$7,510,000);

⁶ For purposes of computing the Net Appraised Sales Price under this subparagraph, deductions may be made only of the portion, if any, of bona fide debts to third parties directly related to the sold or transferred assets and of the Preferred Return on any Investment or portion of an Investment made in the sold or transferred assets

- iv. Between October 2, 2021, and October 1, 2022, eight million, three hundred fifteen thousand dollars (\$8,315,000); and
- v. Between October 2, 2022, and October 1, 2023, nine million, one hundred twenty thousand dollars (\$9,120,000).
- 4. The VAC Defendants shall make all payments required by Paragraph 3 in accordance with instructions to be provided by the Financial Litigation Unit of the United States Attorney's Office for the Southern District of New York.
- 5. The VAC Defendants agree to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Stipulation. Upon reasonable notice, the VAC Defendants shall encourage, and agrees not to impair, the cooperation of their directors, officers, and employees, and shall use their best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. The VAC Defendants further agree to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in their possession, custody, or control concerning any investigation of the Covered Conduct that they have undertaken, or that has been performed by another on their behalf.
- 6. Subject to the exceptions in Paragraphs 11 and 16 below (concerning excluded claims and bankruptcy proceedings), and conditioned upon the VAC Defendants' full compliance with the terms of this Stipulation, including full payment of the Settlement Payments to the United States pursuant to Paragraph 3 above, the United States releases the VAC Defendants, including their subsidiaries and corporate predecessors, successors and assigns, from any civil or administrative monetary claim that the United States has for the Covered Conduct under the FCA, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud

Civil Remedies Act, 31 U.S.C. §§ 3801–3812, and the common-law theories of fraud, payment by mistake, and unjust enrichment. For avoidance of doubt, this Stipulation does not release any current or former officer, director, employee, or agent of the VAC Defendants from liability of any kind.

- 7. The VAC Defendants fully and finally release the United States, its agencies, officers, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that the VAC Defendants have asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, employees, servants, or agents related to the Covered Conduct and the United States' investigation, prosecution and settlement thereof.
- 8. Conditioned on the VAC Defendants' timely payment of all of the Settlement Payments pursuant to Paragraph' 3 above, and fifty thousand dollars (\$50,000) paid to the Relator for reasonable expenses and attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d) when this Stipulation is executed, the Relator, for himself and his heirs, successors, attorneys, agents, and assigns, releases the VAC Defendants and the Non-VAC Defendants, including their respective subsidiaries and corporate predecessors, successors and assigns, as well as all of their current and former officers, directors, employees, attorneys, and other agents, from any and all manner of claims, proceedings, liens, and causes of action of any kind or description that the Relator has against the VAC Defendants and the Non-VAC Defendants.
- 9. In consideration of the execution of this Stipulation by the Relator and the Relator's release as set forth in Paragraph 8 above, the VAC Defendants, including their subsidiaries, predecessors, and corporate successors and assigns, as well as all of their current and former officers, directors, employees, attorneys, and other agents, release the Relator and his

successors, heirs, assigns, attorneys, and other agents, from any and all manner of claims, proceedings, liens, and causes of action of any kind or description that the VAC Defendants have against Relator related to or arising from the Relator Complaint.

- In consideration of the obligations of the VAC Defendants in this Agreement and 10. the Corporate Integrity Agreement ("CIA"), entered into between the Office of Inspector General of the U.S. Department of Health and Human Services ("OIG-HHS") and certain of the VAC Defendants, and conditioned upon the VAC Defendants' timely payment of all of the Settlement Payments, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against the VAC Defendants under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 11 (concerning excluded claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude the VAC Defendants from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 11, below.
- 11. Notwithstanding the releases given in Paragraph 6 above, or any other term of this Stipulation, the following claims of the Government are specifically reserved and are not released by this Stipulation:
 - a. any liability arising under Title 26, United States Code (Internal Revenue Code);
 - b. any criminal liability;

- c. except as explicitly stated in this Stipulation, any administrative liability, including but not limited to the mandatory exclusion from Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7(a) (mandatory exclusion); suspension or debarment pursuant to 2 C.F.R. pt. 376; or actions pursuant to, or otherwise consistent with, 42 C.F.R. § 52.9, 45 C.F.R. §§ 75.207-75.208, or 45 C.F.R. §§ 75.371-75.375;
- d. any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. any liability based upon obligations created by this Stipulation; and
- f. any liability of individuals.
- 12. The VAC Defendants shall be in default of this Stipulation if they fail to make any of the required payments set forth in Paragraph 3 above on or before the due date for each such payment, or if they fail to comply materially with any other term of this Stipulation that applies to them ("Default"). The Government shall provide written notice to the VAC Defendants of any Default in the manner set forth in Paragraph 29 below. The VAC Defendants shall then have an opportunity to cure the Default within ten (10) calendar days from the date of delivery of the notice of Default. In the event that a Default is not fully cured within ten (10) calendar days of the delivery of the notice of Default ("Uncured Default"), interest shall accrue at the rate of 12% per annum compounded daily on the remaining unpaid principal balance of the Maximum Settlement Amount, beginning ten (10) calendar days after mailing of the notice of Default. In the event of an Uncured Default, the VAC Defendants shall agree to the entry of a consent judgment in favor of the United States against the VAC Defendants in the amount of the Maximum Settlement Amount as attached hereto as Exhibit A, provided that, in the event that the VAC Defendants have made one or more Settlement Payments to the United States prior to the Uncured Default, they may, within ten (10) business days of the Uncured Default, execute and deliver to the United States a substitute consent judgment that includes only the amount of

the unpaid balance of the Maximum Settlement Amount. The United States may also, at its option, (a) rescind this Stipulation and reinstate the claims asserted against the VAC Defendants in the Government Complaint (in the event the Government Complaint is reinstated, Relator could also reinstate the claims in the Relator Complaint that he agreed to release pursuant to this Stipulation); (b) seek specific performance of this Stipulation; (c) offset the remaining unpaid balance of the Maximum Settlement Amount from any amounts due and owing the VAC Defendants by any department, agency, or agent of the United States; or (d) exercise any other rights granted by law, or under the terms of this Stipulation, or recognizable at common law or in equity. The VAC Defendants shall not contest any offset imposed or any collection undertaken by the United States pursuant to this Paragraph, either administratively or in any Federal or State court. In addition, the VAC Defendants shall pay the United States all reasonable costs of collection and enforcement under this Paragraph, including attorneys' fees and expenses. In the event that the United States opts to rescind this Stipulation pursuant to this Paragraph, the VAC Defendants shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that relate to the Covered Conduct.

- 13. The Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Stipulation; Relator agrees and confirms that the terms of this Stipulation are fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B).
- 14. The VAC Defendants waive and shall not assert any defenses they may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment

of the Constitution, this Stipulation bars a remedy sought in such criminal prosecution or administrative action.

- 15. The VAC Defendants represent and warrant that they have reviewed their respective financial situations, that, collectively, they are currently not insolvent as such term is defined in 11 U.S.C. § 101(32), that they reasonably believe that they shall remain solvent following payment to the United States of the Settlement Payments, and that, to the extent any individual VAC Center may not be solvent on its own, the remaining VAC Defendants are and will be willing and able to satisfy its financial obligations under this Stipulation. Further, the Parties warrant that, in evaluating whether to execute this Stipulation, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to the VAC Defendants, within the meaning of 11 U.S.C. § 547(c)(1); and (b) have concluded that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which the VAC Defendants were or became indebted to on or after the date of this Stipulation, within the meaning of 11 U.S.C. § 548(a)(1).
- 16. If within 91 days of the Effective Date of this Stipulation or any payment made under this Stipulation, the VAC Defendants, or any of them, commence any case, action, or other proceeding under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors or a third party commences any case, action, or other proceeding under any law related to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking an order for relief of their, or any of their debts, or seeking to adjudicate them, or any of them, as bankrupt or insolvent; or

- (b) seeking appointment of a receiver, trustee, custodian, or other similar official for them, or any of them, or for all or part of their assets, the VAC Defendants agree as follows:
 - a. The obligations of the VAC Defendants, or any of them, under this Stipulation may not be avoided pursuant to 11 U.S.C. § 547, and the VAC Defendants, or any of them, shall not argue or otherwise take the position in any such case, action, or proceeding that (i) their obligations under this Stipulation may be avoided under 11 U.S.C. § 547; (ii) they were insolvent at the time this Stipulation was entered into; or (iii) the mutual promises, covenants, and obligations set forth in this Stipulation do not constitute a contemporaneous exchange for new value given to them.
 - If any of the obligations of the VAC Defendants, or any of them, under b. this Stipulation are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the Government, at its option, may rescind the release in this Stipulation and bring any civil and/or administrative claim, action, or proceeding against the VAC Defendants for the claims that would otherwise be covered by the release in Paragraph 6 above (in the event the Government Complaint is reinstated, Relator could also reinstate the claims in the Relator Complaint that he agreed to release pursuant to this Stipulation). The VAC Defendants agree that (i) any such claim, action, or proceeding brought by the Government would not be subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the case, action, or proceeding described in the first sentence of this Paragraph, and the VAC Defendants, or any of them, shall not argue or otherwise contend that the Government's claim, action, or proceeding is subject to an automatic stay; (ii) the VAC Defendants, or any of them, shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any claim, action, or proceeding that is brought by the Government within 60 calendar days of written notification to them that the release has been rescinded pursuant to this Paragraph, except to the extent such defenses were available on June 29, 2012; and (iii) the Government has a valid claim against the VAC Defendants, jointly and severally, in the amount of the Maximum Settlement Amount and the Government may pursue its claim in the case, action, or proceeding described in the first sentence of this Paragraph, as well as in any other case, action, or proceeding.
 - c. The VAC Defendants acknowledge that the agreements in this Paragraph are provided in exchange for valuable consideration provided in this Stipulation.
- 17. The VAC Defendants have provided sworn financial disclosure statements and other information regarding their financial condition (together, "Financial Statements") to the

United States and the United States has relied on the accuracy and completeness of those Financial Statements in reaching this Stipulation. The VAC Defendants warrant that the Financial Statements are complete, accurate, and current. If the United States learns of any assets in which the VAC Defendants had an interest at the time of this Stipulation that were not disclosed in the Financial Statements, or if the United States learns of any misrepresentation by the VAC Defendants on, or in connection with, the Financial Statements, and if such nondisclosure or misrepresentation changes the net worth of the VAC Defendants as reflected in the Financial Statements by \$100,000 or more, the United States may at its option: (a) rescind this Stipulation and reinstate its suit based on the Covered Conduct (in the event the Government Complaint is reinstated, Relator could also reinstate the claims in the Relator Complaint that he agreed to release pursuant to this Stipulation), or (b) let the Stipulation stand and collect the remaining Settlement Payments plus one hundred percent (100%) of the value of the net worth of the VAC Defendants previously undisclosed. The VAC Defendants agree not to contest any collection action undertaken by the United States pursuant to this provision, and immediately to pay the United States all reasonable costs incurred in such an action, including attorney's fees and expenses.

18. In the event that the United States, pursuant to Paragraph 17 above (concerning disclosure of assets) opts to rescind this Stipulation, the VAC Defendants agree not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that (a) are filed by the United States within 180 calendar days of written notification to the VAC Defendants that this Stipulation has been rescinded, and (b) are based on the Covered Conduct, except to the extent these defenses were available on June 29, 2012.

- 19. The VAC Defendants agree to the following:
 - a. Unallowable Costs Defined: All costs (as defined in the Office of Management and Budget ("OMB") Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards published at 2 C.F.R. pt. 200; the U.S. Department of Health and Human Services' adoption of the OMB Guidance provided at 45 C.F.R. pt. 75, subpart E; the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47, where applicable; or otherwise as specified by federal statutes, regulations or the terms and conditions of a Federal award) incurred by or on behalf of the VAC Defendants, including their present or former officers, directors, employees, and agents in connection with:
 - i. the matters covered by this Stipulation;
 - ii. the United States' audit(s) and civil investigation(s) of matters covered by this Stipulation;
 - iii. the VAC Defendants' investigation, defense, and corrective actions undertaken in response to the United States' audit and civil investigation in connection with the matters covered by this Stipulation (including attorney's fees);
 - iv. the negotiation and performance of this Stipulation;
 - v. the payments the VAC Defendants make to the United States pursuant to this Stipulation and any payments that the VAC Defendants may make to the Relator, including expenses, costs and attorneys' fees; and
 - vi. the negotiation of, and obligations undertaken pursuant to the CIA to: (A) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (B) prepare and submit reports to the OIG-HHS.

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (hereinafter referred to as "Unallowable Costs").

- b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by the VAC Defendants, and the VAC Defendants shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States.
- c. Treatment of Unallowable Costs Previously Submitted for Payment:
 Within 90 days of the Effective Date of this Stipulation, the VAC
 Defendants shall identify and repay by adjustment to future claims for

payment or otherwise any Unallowable Costs (as defined in this Paragraph) included in payments previously sought by the VAC Defendants from the United States. The VAC Defendants agree that the United States, at a minimum, shall be entitled to recoup from them any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted requests for payment. Any payments due shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States, including the Department of Justice and/or the affected agencies, reserves its right to audit, examine, or re-examine the VAC Defendants' books and records and to disagree with any calculation submitted by the VAC Defendants or any of their subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by the VAC Defendants, or the effect of any such Unallowable Costs on the amounts of such payments.

- d. Nothing in this Stipulation shall constitute a waiver of the rights of the United States to audit, examine, or re-examine the VAC Defendants' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.
- 20. This Stipulation is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity except as otherwise provided herein.
- 21. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Stipulation.
- 22. Any failure by the United States to insist upon the full or material performance of any of the provisions of this Stipulation shall not be deemed a waiver of any of the provisions hereof, and the United States, notwithstanding that failure, shall have the right thereafter to insist upon the full or material performance of any and all of the provisions of this Stipulation.
- 23. This Stipulation is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Stipulation is the United States District Court for the Southern District of New York. For purposes of construing this Stipulation, this Stipulation shall be deemed to have been drafted by all Parties to this Stipulation and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

This Stipulation constitutes the complete agreement between the Parties with 24.

respect to the subject matter hereof. This Stipulation may not be amended except by written

consent of the Parties.

The undersigned counsel and other signatories represent and warrant that they are 25.

fully authorized to execute this Stipulation on behalf of the persons and the entities indicated

below.

This Stipulation is binding on the VAC Defendants' successor entities. 26.

This Stipulation is binding on the Relator's successors, transferees, heirs, and 27.

assigns.

This Stipulation may be executed in counterparts, each of which constitutes an 28.

original and all of which constitute one and the same Stipulation. E-mails that attach signatures

in PDF form or facsimiles of signatures shall constitute acceptable, binding signatures for

purposes of this Stipulation.

Any notice pursuant to this Stipulation shall be in writing and shall, unless 29.

expressly provided otherwise herein, be delivered by hand, express courier, or e-mail

transmission followed by postage-prepaid mail, and shall be addressed as follows:

TO THE UNITED STATES:

Jean-David Barnea

Assistant United States Attorney

United States Attorney's Office

Southern District of New York

86 Chambers Street, Third Floor

New York, NY 10007

Email: Jean-David.Barnea@usdoj.gov

21

TO THE VAC DEFENDANTS:

Christopher R. Hall, Esq. Saul Ewing Arnstein & Lehr LLP 1500 Market Street, 38th Floor Philadelphia, PA 19102 Email: chris.hall@saul.com

TO RELATOR:

J. Stephen Simms, Esq.
Simms Showers LLP
201 International Circle, Suite 250
Hunt Valley, MD 21030
Email: jssimms@simmsshowers.com

- 30. The effective date of this Stipulation is the date upon which the Stipulation is approved by the Court (the "Effective Date").
- 31. After the VAC Defendants' final payment to the Government of the Settlement Payments described in Paragraph 3 above, the United States shall be deemed to have dismissed with prejudice the claims asserted by the United States in the Government Complaint (against the VAC Defendants) and the Relator shall be deemed to have dismissed with prejudice the claims he asserted in the Relator Complaint against the VAC Defendants and the Non-VAC Defendants.
- 32. Nothing in this Stipulation affects Relator's claims in the Relator Complaint against any individual or entity other than the VAC Defendants and the Non-VAC Defendants.

SO ORDERED.

THE HONORABLE LORNA G. SCHOFIELD

United States District Judge

10/13/18 Date

Agreed to by:

THE UNITED STATES OF AMERICA

Dated: October New York, New York

GEOFFREY S. BERMAN United States Attorney for the Southern District of New York Counse for the United States

By:

ÆAN-DAVIDÆARNEA Assistant United States Attorney United States Attorney's Office 86 Chambers Street, 3rd Floor

New York, NY 10007 Tel: (212) 637-2679 Fax: (212) 637-2686

Email: Jean-David.Barnea@usdoj.gov

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL

Dated: October 9, 2018 Washington, D.C.

Assistant Inspector General for Legal Affairs Office of Counsel to the Inspector General Office of Inspector General

U.S. Department of Health and Human Services

330 Independence Avenue, SW

Washington, DC 20201

RELATOR

Dated: October 9, 2018 Baltimore, Maryland

SIMMS SHOWERS LLP Counsel for the Relator

By:

J. STEPHEN SIMMS

201 International Circle, Suite 250

Baltimore, MD 21030 Tel: (443) 290-8704 Fax: (410) 510-1789

Email: jssimms@simmsshowers.com

Dated: October 9, 2018 Kingston, New York

MICHAEL I. LEVINE, M.D.

Relator

DEFENDANTS

Dated: October <u>9</u> , 2018 Philadelphia, Pennsylvania		SAUL EWING ARNSTEIN & LEHR LLP Counsel for the VAC Defendants
	Ву:	CHRISTOPHER R. HALL 1500 Market Street, 38th Floor Philadelphia, PA 19102 Tel: (215) 972-7180 Fax: (215) 972-1917 Email: chris.hall@saul.com
Dated: October		VASCULAR ACCESS CENTERS, L.P. by Vascular Access Centers, LLC, its General Partner
	Ву:	James F. McGackin, M.D. General Partner
Dated: October, 2018 Philadelphia, Pennsylvania		VASCULAR ACCESS CENTER OF ATLANTA LLC, by Vascular Access Centers, LLC, its Manager
	Ву:	James F. McGuckin, M.D. Manager
Dated: October2018 Philadelphia, Pennsylvania		VASCULAR ACCESS CENTER OF ATLANTIC COUNTY LLC, by Vascular Access Centers, LLC, its Manager
	Ву:	James F. McGuckin, M.D. Manager
Dated: October, 2018 Philadelphia, Pennsylvania		VASCULAR ACCESS CENTER OF BOLIVAR COUNTY LLC, by Vascular Access Centers, LLC, its Manager
	Ву:	James F. McGuekin, M.D.

Dated: October, 2018 Philadelphia, Pennsylvania		VASCULAR ACCESS CENTER OF CENTRAL JERSEY LLC, by Vascular Access Centers, LLC, its Manager
	Ву:	James F. McGuckin, M.D. Manager
Dated: October 4, 2018 Philadelphia, Pennsylvania		VASCULAR ACCESS CENTER OF DURHAM LLC, by Vascular Access Centers, LLC, its Manager
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	Ву:	James F. McGuckin, M.D. Manger
Dated: October, 2018 Philadelphia, Pennsylvania		VASCULAR ACCESS CENTER OF WEST ORANGE LLC by Vascular Access Centers, LLC, its Manager
	Ву:	James F. McGuckin, M.D.

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel*. MICHAEL I. LEVINE, M.D.,

Plaintiff,

VASCULAR ACCESS CENTERS, L.P., and each of its subsidiary and/or related corporations, *et al.*,

Defendants.

UNITED STATES OF AMERICA,

v.

Plaintiff-Intervenor,

v.

VASCULAR ACCESS CENTERS, L.P., and each of its subsidiary and/or related corporations,

Defendants.

12 Civ. 5103 (LGS)

CONSENT JUDGMENT

Upon the consent of plaintiff the United States of America and defendant Vascular Access Centers, L.P., and each of its subsidiary and/or related corporations (together, the "VAC Defendants")⁷ it is hereby

⁷ In addition to Vascular Access Centers, L.P., the VAC Defendants consist of Vascular Access Center of Atlanta LLC; Vascular Access Center of Atlantic County LLC; Vascular Access Center of Bolivar County LLC; Vascular Access Center of Central Jersey LLC; Vascular Access Center of Durham LLC; Vascular Access Center of Eatontown LLC; Vascular Access Center of Georgia LLC; Vascular Access Center of Houston LLC; Vascular Access Center of Jacksonville LLC; Vascular Access Center of Jersey City LLC; Vascular Access Center of Memphis LLC; Vascular Access Center of New Orleans LLC; Vascular Access Center of North Shore Louisiana LLC; Vascular Access Center of Pittsburgh LLC; Vascular Access Center of Prince George County LLC; Vascular Access Center of Seattle LLC; Vascular Access Center of South Atlanta LLC; Vascular Access Center of South Los Angeles LLC; Vascular Access Center

ORDERED, ADJUDGED and DECREED: that plaintiff the United States of America is awarded judgment as against the VAC Defendants, jointly and severally, in the amount of eighteen million, three hundred sixty thousand, seven hundred ninety-four dollars (\$18,360,794), plus interest accruing annually at a rate of 2.125% from July 9, 2018, to the date of this judgment, as well as post-judgment interest at the rate of 12% per annum compounded daily.

SO ORDERED.		
THE HONORABLE LORNA G. SCHOFIELD United States District Judge	Date	

of Southern Maryland LLC; Vascular Access Center of Southwest Louisiana LLC; Vascular Access Center of Trenton LLC; Vascular Access Center of Washington DC LLC; and Vascular Access Center of West Orange LLC.

Agreed to by:

THE UNITED STATES OF AMERICA

Dated: October <u>1</u>, 2018 New York, New York

GEOFFREY S. BERMAN United States Attorney for the Southern District of New York Counsel for the United States

By:

JEAN-DAVID BARNEA Assistant United States Attorney United States Attorney's Office 86 Chambers Street, 3rd Floor New York, NY 10007

Tel: (212) 637-2679 Fax: (212) 637-2686

Email: Jean-David.Barnea@usdoj.gov

DEFENDANTS

Dated: October <u>9</u> , 2018 Philadelphia, Pennsylvania		SAUL EWING ARNSTEIN & LEHR LLP Counsel for the VAC Defendants
	Ву:	CHRISTOPHER R. HALL 1500 Market Street, 38th Floor Philadelphia, PA 19102 Tel: (215) 972-7180 Fax: (215) 972-1917 Email: chris.hall@saul.com
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